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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,201	08/22/2000	Gerardo V. Noriega	19635-000210US	1112

20350 7590 05/07/2003

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EXAMINER

NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/644,201

Applicant(s)

NORIEGA ET AL.

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27-39, 67-70 and 72-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-39 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-20, 22, 23, 25-30, 67-70 and 72-80 is/are rejected.
- 7) ☒ Claim(s) 14, 21, 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13, 15-20, 22-23, 25, 27-30, 67-70, 72-74, 76-78 and 80 are rejected under 35 U.S.C. 102 (e) as being clearly anticipated by Ressemann et al (U.S. 5,897,567).

As to claims 1 and 80, Ressemann et al discloses in figs 1 and 10 an assembly having all the limitation as recited in the above listed claim, including: a guide wire (90 is considered a guide-wire, labeled in col. 11, lines 41-45); a drive shaft (92, labeled in col. 11, lines 51-54), wherein said drive shaft (92) includes a distal tip (figs 10) which can create a path through stenotic material.

As to claims 2 and 5-8, Ressemann et al discloses in figs 1 and 10; wherein the guide wire (90) has a diameter about 0.072"(col.11, lines45-47); wherein the assembly further including a detachable motor (24) coupled to the drive shaft (92), wherein said proximal end of the drive shaft can be manually rotated; the distal tip is flattened and twisted (col. 13, lines 4-14 and lines 59-64); and wherein the distal end of the hollow guide wire (90) is steerable.

Since the guidewire has diameter about 0.072" larger than 0.035", however, the device is inherently capable of being used to insert into blood vessel.

As to claims 9-12, Ressemann et al discloses in figs 1 and 10; wherein a housing (36) coupled to the proximal end of the hollow guide wire; wherein said housing (36) including an actuator (52), wherein the drive shaft (92) defines a longitudinal axis and the actuator (52) moves the drive shaft along the longitudinal axis; wherein the actuator (52) can extend the drive shaft up to 5 centimeters beyond the distal end of the hollow guide wire (90); and wherein the housing (36) includes an aspiration port (80, 82 , fig 2) coupled to the hollow guide wire.

As to claims 13 and 15, Ressemann et al discloses in figs 1 and 10; wherein the guide wire (90) is in stationary position while the drive shaft (92) facilitates transportation of a removed occlusive material.

As to claims 16-19, Ressemann et al discloses in figs 1 and 10; wherein a support system having a distal end, wherein the hollow guide wire (90) passes through the support system in order to allow the distal tip is positioned beyond the distal end of the hollow guide wire and the support system; wherein the support system includes placing means disposed near distal end of the support system within the body lumen; and wherein the hollow guide wire is through a vasculature and the drive shaft (92) defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

As to claim 20, Ressemann et al discloses in figs 1 and 10 an assembly having all the limitation as recited in the above listed claim, including: a hollow guide wire (90); a rotating mechanism coupled to the drive shaft (92); wherein an actuator (52) coupled to the drive shaft (92); and wherein the activation of the actuator (52) advances the rotatable drive shaft (92) from a retracted position to an extended position; wherein said drive shaft (92) including a distal tip (figs 1 and 10) can be rotated and created a path through stenotic material.

As to claims 22-23, Ressemann et al discloses in figs 1 and 10, wherein the distal tip portion creates a path forward of the hollow guide wire (90).

As to claims 25, 27-30, Ressemann et al discloses in figs 1 and 10, wherein the hollow guide wire (90) is advanced through a body lumen without the need of a separate guide wire; wherein the rotating mechanism and actuator (52) are coupled together, wherein the rotating mechanism and actuator (52) are independently rotated and advanced; and wherein the rotating mechanism is removably attached to the drive shaft (92); wherein the lumen of the hollow guide wire aspirated fluids and debris from stenosis.

As to claim 67, Ressemann et al discloses in figs 1 and 10 an assembly having all the limitation as recited in the above listed claim, including: a hollow guide wire (90); a rotatable drive shaft (92) having a shaped distal tip, the rotatable wire received within the passage of the hollow guide wire; and wherein the rotating inner wire is within the guide wire and advancing the drive shaft (92) into the occlusive material; wherein a package contained the hollow guide wire, rotatable wire and the instructions for use.

As to claims 68-70 and 72, Ressemann et al discloses in figs 1 and 10; wherein the rotation of the distal tip creates at least as large as the outer diameter of the hollow guide wire (90), wherein said hollow guide wire has a diameter about 0.072 inches (col.11, lines 45-47) and has a steerable distal portion.

As to claims 73-74 and 76-78, Ressemann et al discloses in figs 1 and 10, wherein the kit further including a support system is sized to received the hollow guide wire (90) and a guiding catheter (14); wherein the kit further including a power supply and a motor (24) and an

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attachment mechanism for detachably coupling the motor (24) to the drive shaft (92); wherein the power supply includes a sheath cover (40,58).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75 and 79 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ressemann et al in view of Noriega (U.S. 6,059,767).

As to claim 75, Ressemann teaches all aspect of the claimed invention except including a second guide wire, wherein the support system is advanced through the body lumen over the second guidewire. Noriega teaches a second guide wire, wherein the support system is advanced through the body lumen over the second guidewire (col. 4, lines 45-67 and col. 5, lines 1-14) in order to improve the efficiency of the catheter and to provide a better positioned at a selected tissue site. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ressemann by adding a second guide wire, wherein the support system is advanced through the body lumen over the second guide wire in order to improve the efficiency of the catheter and to provide a better positioned at a selected tissue site.

As to claim 79, Ressemann teaches all aspect of the claimed invention except the housing is coupled to the hollow guide wire through a luer. Noriega teaches the housing is coupled to the hollow guide wire through a luer (see figs 2, 4 and 5) in order to facilitate fluids going through the guide wire. It would have been obvious to one of ordinary skill in the art at the time of the

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invention to modify Ressemann by adding the housing is coupled to the hollow guide wire through a luer in order to facilitate fluids going through the guide wire.

Allowable Subject Matter

3. Claims 31-39 are allowed.

Claims 14, 21 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest all of the limitations of the claims including: a flattened and twisted distal tip is attached to the drive shaft that can create a path in front of the elongate member; and wherein the distal tip of the drive shaft is radio-opaque.

Response to Arguments

4. Applicant's arguments filed 2/24/2003 have been fully considered but they are not persuasive. With respect to claims 1, 20, 67 and 80, according to the Applicant, since Rossemann et al do not describe the configuration in which a drive shaft extends through the axial passage of the guidewire and the drive shaft movably disposed within the guidewire as recited in claims 1, 20, 67 and 80. The examiner, respectfully, disagrees. The expandable removal device (10, figures 1 and 10 of Rossemann et al '567) is inherently capable of performing the same function as the applicant's device to remove occlusive material and passing through occlusions, stenosis and other material in a body lumen. Furthermore, the Rossemann et al' device do disclose the configuration in which a drive shaft (92) extends through the axial passage of the guidewire (90) and the drive shaft movably disposed within the guidewire (figs 1,

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10, abstract and col. 11, lines 41-45 and lines 51-54). Therefore, the claimed invention is not patentable over the Rossemann et al' device.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen
Examiner
Art Unit 3731

vn ✓
May 5, 2003


KEVIN T. TRUONG
PRIMARY EXAMINER

5/5/03